

PCT

10/527703

INTERNATIONAL PRELIMINARY EXAMINATION REPORT



(PCT Article 36 and Rule 70)

Applicant's or agent's file reference M863-PCT	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PA/416)	
International application No. PCT/JP 03/1744	International filing date (day/month/year) 12.09.2003	Priority date (day/month/year) 13.09.2002
International Patent Classification (IPC) or both national classification and IPC C12P7/64		
Applicant SUNTORY LIMITED, et al.		

- This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
- This REPORT consists of a total of 8 sheets, including this cover sheet.
 - ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheets.

- This report contains indications relating to the following items:
 - I ☒ Basis of the opinion
 - II ☐ Priority
 - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
 - IV ☐ Lack of unity of invention
 - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
 - VI ☐ Certain documents cited
 - VII ☐ Certain defects in the international application
 - VIII ☐ Certain observations on the international application

Date of submission of the demand 13.04.2004	Date of completion of this report 13.01.2005
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International application No. **PCT/JP 03/11744**

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, Pages

1-37 as originally filed

Claims, Numbers

1-30 as originally filed

Drawings, Sheets

1/1 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
☐ the language of publication of the international application (under Rule 48.3(b)).
☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority in written form.
☐ furnished subsequently to this Authority in computer readable form.
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
☐ the claims, Nos.:
☐ the drawings, sheets:

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5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	2,8,16,20
	No: Claims	1,3-7,9-15,17-19,21-30
Inventive step (IS)	Yes: Claims	
	No: Claims	1-30
Industrial applicability (IA)	Yes: Claims	1-30
	No: Claims	

2. Citations and explanations

see separate sheet

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Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

- 1). The documents mentioned in the International search report are cited by the following abbreviations:
 - D1: PATENT ABSTRACTS OF JAPAN vol. 1999, no. 02, 26 February 1999 (1999-02-26) -& JP 10 290699 A (NIPPON SYNTHETIC CHEM IND CO LTD;THE; SHIMADA YUJI), 4 November 1998 (1998-11-04)
 - D2: TANE K ET AL: "PREPARATION OF POLYUNSATURATED OIL BY REPEATED TRANSESTERIFICATION WITH LIPASE" YUKAGAKU - JOURNAL OF THE JAPAN OIL CHEMISTS' SOCIETY, NIHON YUKAGAKU KYOKAI, TOKYO, JP, vol. 46, no. 7, 1997, pages 785-790, XP008012635 ISSN: 0513-398X
 - D3: PATENT ABSTRACTS OF JAPAN vol. 2000, no. 04, 31 August 2000 (2000-08-31) -& JP 2000 004894 A (SUNTORY LTD; OSAKA CITY), 11 January 2000 (2000-01-11)
 - D4: PATENT ABSTRACTS OF JAPAN vol. 1996, no. 12, 26 December 1996 (1996-12-26) -& JP 08 214891 A (OSAKA CITY; MARUHA CORP), 27 August 1996 (1996-08-27)
 - D5: PATENT ABSTRACTS OF JAPAN vol. 1995, no. 01, 28 February 1995 (1995-02-28) -& JP 06 287593 A (SNOW BRAND MILK PROD CO LTD), 11 October 1994 (1994-10-11)
- 2). The **present patent application** concerns in **claims 1-9** a transesterification process using a 1,3-specific lipase for the production of transesterified fats/oils/triglycerides, starting from fungus produced oils/fats/triglycerides and optionally adding a vegetable oil/fat/TG. **Claims 21-23** claim a similar process but specify that 0-50% have to be medium chain fatty acid triglycerides.
Claims 10-16 and 24 are directed to products obtained by the process of claims 1-9 and are drafted as so-called "product-by-process"-claims.
Claims 17-20, 25 and 26 are independent product claims directed to oils/fats/triglycerides.
Claims 27-30 claim compositions comprising the above products and are for human nutrition, undefined food and animal feed.
- 3). **The following serious deficiencies have been identified in the present**

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application:

- a) The present patent application consists of 18 (!!) independent claims amongst a total number of claims of 30. Although claims 1, 10-21, 24, 25, 27, 28 and 30 all have been drafted as separate independent claims, they appear to relate effectively to the same subject-matter and to differ from each other only with regard to the definition of the subject-matter for which protection is sought and/or in respect of the terminology used for the features of that subject-matter. The aforementioned claims therefore lack conciseness and as such do not meet the requirements of Article 6 and Rule 6 PCT.
- b) Claims 10-16 and 24 are defined as "product-by process claims", that means that a product is claimed but defined by its way of preparation. A warning is therefore given to the applicant that, when entering the national/regional phase, at least under the EPC such a claim is only regarded as novel and inventive if the product per se fulfils the requirements for novelty and inventive step.
- c) The product claims 17-20, 25 and 26 are drafted in a confusing way, so that they are obscure (Art. 6 PCT). Since it is unclear what is embraced by their scope, they are interpreted in the broadest possible way.
- d) The term "medium chain" in e.g. claim 21 is obscure since it is not clear what is embraced by "medium" (art. 6 PCT).
- 4). **Brief discussion of the prior art documents:**

D1 discloses the same transesterification process as claimed in present claims 1-9 and 21-23, whereby D1 does not mention a fungal oil as starting material. D1 specifies gamma-linolenic acid and dihomogamma-linolenic acid as well as caprylic acid (=octanoic acid). The lipase originates from *Rhizopus delemar*. The produced fats and oils are useful especially in health foods and have a high storage stability (= are less sensitive to oxidation).

D2 describes the transesterification of tuna oil using a lipase from *Rhizomucor miehei*. DHA and EPA are mentioned as fatty acids.

D3 concerns the transesterification of a triglyceride containing a medium chain fatty acid at position 1 and 3 with omega 3, omega 6 or omega 9 type unsaturated

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fatty acids in the presence of a lipase and reports that the yielding fat has a structure similar to that of mother's milk.

D4 discloses a transesterification process for the preparation of a fat/oil which contains a medium chain fatty acid (preferably octanoic acid), arachidonic, docosahexaenoic acid or eicosapentaenoic acid.

The produced fat/oil is useful in drugs, biochemical reagents and foods.

D5 describes a transesterification reaction yielding fats/oils with improved oxidation stability and good nutrition physiological functions. The fatty acids mentioned in D5 are arachidonic acid, linoleic acid, etc.

5). **Novelty - Art. 33(1) and (2) PCT:**

Since it is not clear whether the term "fungal oil" is a feature that clearly delimits the present starting material from D1 - D5, it is presently assumed as being not a distinguishing feature. The claimed process is not drafted as a multistep process, starting with the production of the fungal oil using a fungus, which is then transesterified, but starts with the isolated fat/oil as the starting material. Since neither the fungus nor the reaction conditions for the production of the fungal oil are specified, it is assumed that the starting material is the same as in the prior art, no matter that it has been produced by a fungus.

Therefore the claimed subject-matter lacks novelty in the light of D1, D2, D4 and D5.

D1 destroys the novelty of claims 1, 3, 4, 6, 7, 9-15, 17, 19, 21, 23, 24 and 26-30.

D2 is an obstacle to the novelty of claims 1, 3, 4, 9-13, 17, 21, 23 and 27-30.

D4 is novelty destroying for claims 1, 3-5, 9-14, 17, 18, 21-25 and 27-30.

D5 is an obstacle to the novelty of claims 1, 3-5, 10-14, 17, 18, 21, 22, 24, 25 and 27-30.

**Summarising, claims 1, 3-7, 9-15, 17-19 and 21-30 lack novelty.
Only claims 2, 8, 16 and 20 appear to be new.**

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6). **Inventive step - Art. 33(1) and (2) PCT:**

As stated in § 5) above, claims 1, 3-7, 9-15, 17-19 and 21-30 lack novelty and therefore an inventive step cannot be acknowledged.

Although the specific features mentioned in claims 2, 8, 16 and 20 appear to be new, an inventive step cannot be acknowledged, either.

The problem underlying the present patent application as stated on p. 5 and 8 of the description is to provide compounds that are useful in the fields of modified milk for infants (approaching the structural form of human breast milk), food products and healthy foods and/or supplements, which exhibit properties such as ready digestions and absorption and resistance to oxidative damage. This problem has already been solved by the products provided by prior art documents D1-D5 (see § 4) above) .

Therefore, the problem underlying the present application can only be seen in providing products with a superior effect in comparison to those of the prior art. The difference between **claim 2** and the prior art is the feature that the transesterification reaction is conducted in a deoxygenated state. No superior effect or activity or surprising property is stated to be based on the said feature. Claim 2 therefore lacks an inventive step.

Claims 8, 16 and 20 specify mead acid (5, 8, 11-eicosatrienoic acid) as a component of the produced fat/oil.

Again, in the absence of any evidence that a superior effect or activity or surprising property is based on the presence of mead acid in the produced fat/oil, an inventive step cannot be acknowledged.

Summarising, claims 1-30 lack an inventive step.

7). **Industrial applicability - Art. 33(1) and (4) PCT:**

The subject-matter of claims 1-30 is industrially applicable.

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